REMARKS/ARGUMENTS

The Pending Claims

Claims 1-92 currently are pending. Claims 1-51 and 62-92 have been withdrawn in response to a restriction requirement. As such, claims 52-61 currently are subject to examination. With respect to claims that have been withdrawn, upon allowance of one or more elected product claims, Applicants request rejoinder of the withdrawn method claims dependent on any of the allowed claims or which otherwise contain the limitations of an allowed claim.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. Claim 52 has been amended to specify that the pharmaceutical composition comprises an immune suppressing agent. Support for this amendment can be found in the specification at, for example, page 40, lines 2-6. No new matter has been added by way of these amendments.

The Office Action

Claims 52-61 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 4,810,643 (Souza) ("the '643 patent"), Arpinati et al., *Blood*, 95: 2484-2490 (2000) ("the Arpinati reference"), Molineux et al., *Experimental Hematology*, 27: 1724-1734 (1999) ("the Molineux reference") as evidenced by Kinstler et al., *Adv. Drug Del. Rev.*, 54: 477-485 (2002) ("the Kinstler reference"), Willis et al., *Expert Opin. Biol. Ther.*, 2: 985-992 (2002) ("the Willis reference"), and Li, *J. Pharmacy Soc. Wisconsin*, May/June, 34-39 (2003) ("the Li reference"). Claims 52-61 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Pan et al., *Blood*, 93: 4071-4078 (1999) ("the Pan reference") in view of deHaan et al., *British J. Haematol.*, 110: 638-646 (2000) ("the deHaan reference"), and U.S. Patent 5,320,840 (Camble et al.) ("the '840 patent").

Discussion of Rejection Under 35 U.S.C. § 102(b)

Claims 52-61 have been rejected as allegedly anticipated by the '643 patent, the Arpinati reference, the Molineux reference as evidenced by the Kinstler reference, the Willis reference, and the Li reference.

Claim 52 has been amended to specify that the pharmaceutical composition comprises a G-CSF derivative or biologically active fragment, homolog, or variant thereof, an immune suppressing agent, and a pharmaceutically-acceptable carrier. In contrast to the invention recited in claim 52 and claims depending thereon, the '643 patent merely discloses a pharmaceutical composition comprising human G-CSF polypeptides and variants thereof (e.g., deletion analogs, substitution analogs, and addition analogs) that may be used for the treatment of hematopoietic disorders.

The Arpinati reference discloses that G-CSF treatment mobilizes lymphoid dendritic cells, but not myeloid dendritic cells, and that G-CSF has been used to mobilize hematopoietic stem cells from the bone marrow into the bloodstream. The Molineux reference merely teaches the use of filgastrim and pegylated filgastrim to treat chemotherapy-induced neutropenia. The Willis reference discloses the use of non-glycosylated filgastrim and pegylated filgastrim for reducing the incidence of chemotherapy induced neutropenia. The Li reference is directed to the use of pegylated filgastrim for reducing the incidence of febrile neutropenia in patients with non-myeloid cancers receiving myelosuppressive chemotherapy.

None of the cited references discloses or suggests a pharmaceutical composition comprising an immune suppressing agent in combination with a G-CSF derivative or biologically active fragment, homolog, or variant thereof and a pharmaceutically-acceptable carrier, as recited in pending claim 52, and claims 53-61 depending thereon. Accordingly, the anticipation rejection of claims 52-61 should be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 103(a)

Claims 52-61 have been rejected as allegedly obvious over the Pan reference in view of the deHaan reference and the '840 patent.

The Pan reference discloses that G-CSF-mobilized allogeneic peripheral blood stem cell transplantation reduces the severity of acute graft-versus-host disease while maintaining perforin-dependent graft-versus-leukemia effects. The Pan reference does not disclose or suggest a pharmaceutical composition comprising the combination of (a) a G-CSF derivative or biologically active fragment, homolog, or variant thereof, (b) an immune suppressing agent, and (c) a pharmaceutically-acceptable carrier, as recited in the rejected claims.

The deHaan reference and the '840 patent, either alone or in combination, do not compensate for the deficiencies of the Pan reference. In particular, neither the deHaan nor the '840 patent discloses or suggests the use of an immune suppressing agent in a pharmaceutical composition in combination with a G-CSF derivative or biologically active fragment, homolog, or variant thereof and a pharmaceutically-acceptable carrier, as recited in pending claim 52, and claims 53-61 depending thereon.

In view of the foregoing, the combination of cited references does not disclose or suggest the present invention as recited in pending claims 52-61, and the obviousness rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: December 1, 2008